09-14-07

Attorney's Docket No.: 17248-004002 / 4804B

# THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Aladar Szalay et al.

Art Unit : 1633

Serial No.:

10/849,664

Examiner: Robert M. Kelly

Filed

: May 19, 2004

Cust. No. : 20985 Conf. No.: 7765

Title

: LIGHT EMITTING MICROORGANISMS AND CELLS FOR DIAGNOSIS

AND THERAPY OF DISEASES ASSOCIATED WITH WOUNDED OR

**INFLAMED TISSUE** 

## Mail Stop Amendment

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### TRANSMITTAL

#### Dear Sir:

Transmitted herewith are a Supplemental Information Disclosure Statement, Form PTO-1449 (3 pages), cited non U.S. patent documents listed on the form PTO-1449, documents listed in table of Supplementary Information Disclosure Statement (3 documents, including 2 European Examination Reports), and a return postcard for filing in connection with the above-captioned application. Because this Supplemental Information Disclosure Statement is filed with a Request for Continued Examination and prior to receipt of a first Office Action on the merits for the above-captioned application, a fee for filing this statement should not be due. However, should it be determined that a fee for filing these papers is required, the Commissioner is authorized to charge Deposit Account No, 06-1050, as stated below:

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The Commissioner is hereby authorized to charge the fee for the extension of time and any other fee that may be due in connection with this and the attached papers or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

Stephanie Seidman Reg. No. 33,779

Attorney's Docket No.: 17248-004002 / 4804B

Address all correspondence to:

Stephanie Seidman Fish & Richardson P.C. 12390 El Camino Real San Diego, California 92130 Telephone: (858) 678-4777 Facsimile: (202) 626-7796

email: seidman@fr.com

CERTIFICATE OF MAILING BY "EXPRESS MAIL" "Express Mail" Mailing Label Number EV 965983427 US

Date of Deposit September 12, 2007

I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria VA, 22313-1450.

Stephanie Scidnar

Attorney's Docket No.: 17248-004002 / 4804B

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Aladar Szalay et al. Art Unit : 1633

Examiner: Robert M. Kelly Serial No.: 10/849,664

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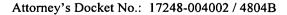
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Stephanie Seidma





#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Aladar Szalay et al. Art Unit: 1633

Serial No.: 10/849,664 Examiner: Robert M. Kelly

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Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98

This Supplemental Information Disclosure Statement is filed with a Request for Continued Examination of the above-captioned application and prior to receipt of an Office Action. Thus, a fee for filing this statement should not be due. If, however, it is determined that a fee is due, any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Forms PTO-1449 (3 pages) and copies of the cited non U.S. Patent documents are provided herewith in connection with the above-captioned application.

The documents cited on the Form PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

In accordance with the requirements of 37 C.F.R. §1.98, the following documents are provided for consideration by the Examiner:

CERTIFICATE OF MAILING BY "EXPRESS MAIL" "Express Mail" Mailing Label Number EV 965983427 US

Date of Deposit September 12, 2007 I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents. 4.8. Patent and Trademark Office,

P.O. Box 1450, Alexandria, XA 22313-1450.

Stephanie Seidman

Applicant: Szalay et al.

Serial No.: 10/849,664

Filed: May 19, 2004

Attorney's Docket No.: 17248-004002 / 4804B

Supplemental Information Disclosure Statement

1) Examination Report, issued October 26, 2005, in connection with European Patent Application No. 02012552.2 (Attorney Docket No. 17248-004EP1/4804EP).

- 2) Examination Report, issued June 22, 2007, in connection with European Patent Application No. 03735553.4 (Attorney Docket No. 17248-004EP2/4804BEP).
- 3) "Definition of Tumor", MedicineNet.com, www.medterms.com/script/main/art.asp?articlekey=5863 (Accessed on May 30, 2007).

The table below lists Documents 1-3 and includes a column that provides a space next to each document to be considered, for the Examiner's initials.

Examiner Initial	Document No.	Document
	1	Examination Report, issued October 26, 2005, in connection with European Patent Application No. 02012552.2.
	2	Examination Report, issued June 22, 2007, in connection with European Patent Application No. 03735553.4
	3	"Definition of Tumor", MedicineNet.com, www.medterms.com/script/main/art.asp?articlekey=5863 (Accessed on May 30, 2007)

Applicant also makes known to the Examiner the following U.S. and international applications, which are commonly owned and/or have one or more inventors in common.

Seria	al No.	Filing Date	Docket No.
11/5	29,662	09/27/06	17248-002003/4802C
11/79	96,028	04/25/07	17248-002004/4802D
11/7	96,027	04/25/07	17248-002005/4802E
10/5	16,785	06/27/05	17248-004US1/4804US
11/8	27,518	07/11/07	17248-012001/4812
Seria	al No.	Filing Date	Docket No.
PCT	/US2007/15829	07/11/07	17248-012WO1/4812PC

Attention is directed to copending U.S. Patent Application Serial No. 10/516,785 filed June 27, 2005, which is a national stage application of International Patent Application No. PCT/EP03/05907, filed June 5, 2003, that claims priority to European Application No. 02012552.2, filed June 5, 2002. The instant application and the copending application include claims directed to methods of detection/visualization of wounds, wounded tissues, inflammation sites and inflamed tissues. The inventive entity listed on the instant application differs from the inventive entity in the copending application. Applicant is reviewing inventorship.

Applicant: Szalay et al. Serial No.: 10/849,664

Filed : May 19, 2004

Attorney's Docket No.: 17248-004002 / 4804B Supplemental Information Disclosure Statement

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the information, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing documents and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

Stephanie Seidman Reg. No. 33,779

Attorney's Docket No.: 17248-004002 / 4804B

Address all correspondence to:

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Telephone: (858) 678-4777 Facsimile: (202) 626-7796 email: seidman@fr.com

Substitute Form PTO-1449 (Modified)

SEP 1 2 2007

S. Department of Commerce

Attorney's Docket No. 17248-004002/4804B Application No. 10/849,664

List of Paterits and Publications for Applicant's Information Distribution Statement

Applicant Aladar Szalay et al.

Filing Date May 19, 2004 Group Art Unit 1633

(37 CFR §1.98(b))

	U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate	
	AA	2003/0103941	06/05/03	Crombleholme et al.	424	93.2	10/09/02	
	AB	2005/0063993	03/24/05	Schlom et al.	424	199.1	01/14/03	
	AC	2007/0025981	02/01/07	Szalay et al.	424	130.1	09/27/06	
•	AD	2007/0202572	08/30/07	Szalay et al.	424	199.1	04/25/07	
·	AE	5,833,975	11/10/98	Paoletti et al.	424	93.2	01/19/94	
	AF	6,045,802	04/04/00	Schlom et al.	424	199.1	06/07/95	
	AG	6,106,826	08/22/00	Brandt et al.	424	93.2	12/17/97	
	AH	6,503,703	01/07/03	Palese et al.	435	5	08/11/00	
	AI	6,548,068	04/15/03	Schlom et al.	424	199.1	01/07/00	

	Foreig	n Patent Doc	uments or P	ublished Foreign P	atent A	Application	าร	
Examiner	Desig.	Document	Publication	Country or			Trans	slation
Initial	ID	Number	Date	Patent Office	Class	Subclass	Yes	No
	AJ	98/35695	08/20/98	WIPO				

	Other Documents (include Author, Title, Date, and Place of Publication)			
Examiner	Desig.			
Initial	ID	Document		
	AK	Byun, J., et al. "Myocardial injury-induced fibroblast proliferation facilitates retroviral-mediated gene transfer to the rat heart <i>in vivo</i> ," Journal of Gene Medicine, 2:2-10, (2000).		
	AL	Chaloupka, I., et al., "Comparative analysis of six european influenza vaccines" European Journal of Clinical Microbiology and Infectious Disease," 15(2):121-127 (1996)		
	AM	Chen, Y., "Orthopedic applications of gene therapy," Journal of Orthopedic Science, 6:199-207, (2001).		
	AN	Chernajovsky, Y., et al., "Fighting cancer with oncolytic viruses," British Medical Journal, 332(7534):170-172, (2006).		
	AO	Crombleholme, T., "Adenoviral-mediated gene transfer in wound healing," Wound Repair and Regeneration, 8:460-472, (2000).		
	AP	Cupp, C. and D. Bloom, "Gene therapy, electroportation, and the future of wound-healing therapies," Facial Plastic Surgery, 18:53-57, (2002).		
	AQ ·	Deodato, B., et al. "Recombinant AAV vector encoding human VEGF165 enhances wound healing," Gene Therapy, 9:777-785, (2002).		
	AR	Eming, S., et al. "Gene therapy for tissue repair:approaches and prospects," British Journal of Plastic Surgery, 50:491-500, (1997).		
	AS	Fox, M., et al., "Anaerobic bacteria as a delivery system for cancer gene therapy: in vitro activation of 5-fluorocytosine by genetically engineered clostridia," Gene Therapy, 3(2):173-178, (1996).		

Examine	r Signature
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Date Considered

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

				Sheet <u>2</u> 01 <u>3</u>	
Substitute For (Modified)	m PTO-1449	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 17248-004002/4804B	Application No. 10/849,664	
		d Publications for Applicant's n Disclosure Statement	Applicant Aladar Szalay et al.		
(37 CFR §1.98	3(b))		Filing Date May 19, 2004	Group Art Unit 1633	
	Other D	ocuments (include Author, 1	Title, Date, and Place of	f Publication)	
Examiner Initial	Desig. ID		Document		
	AT	Fox, M., et al., Erratum to "Anaerobic activation of 5-fluorocytosine by gene	etically engineered clostridia," G	ene Therapy, 3(8):741, (1996).	
	AU	Furlan, R., et al., "Central nervous systongoing relapsing-remitting autoimmed 8:13-19, (2001).	une encephalomyelitis in Biozzi	AB/H mice," Gene Therapy,	
	AV	Gautam, A., et al., "Delivery systems Medicine, 1(1):35-46, (2002).		• •	
	AW	Gordon, E., et al., "Lesion-targeted in Therapy, 12:1277-1287, (2001).			
	AX	Gura, T., "Systems for identifying nev	w drugs are often faulty," Science	e, 278:1041-1042, (1997).	
	AY	Hall, F., et al., "Targeting retroviral ve MoMLV gp70 envelope protein," Hur			
	AZ	Hogaboam, C., et al., "Therapeutic effects of interleukin-4 gene transfer in experimental inflammatory bowel disease," Journal of Clinical Investigation, 100(11):2766-2776, (1997).			
	BA	Hogervorst, E., et al., "Modulation of experimental autoimmunity:treatment of adjuvant arthritis by immunization with a recombinant vaccinia virus," Infection Immunity, 59(6):2029-2035, (1991).			
	ВВ	Kelland, L., "Of mice and men:values drug development," European Journal	and liabilities of the athymic nu		
	BC	Kerbel, R., "Human tumor xenografts humans," Cancer Biology & Therapy,	as predictive preclinical models		
	BD	Kirn, D., et al. "A tale of two trials: se Therapy, 7(10):815-816, (2000).		·	
	BE	Kohler, G. and C. Milstein, "Continuo specificity," Nature, 256:495-497, (19	75).		
	BF	Larocca et al., "Gene Transfer to Man Bacteriophage," FASEB Journal, 13:7	727-734, (1999).		
	BG	Liechty, K., et al., "Adenoviral-media ischemic Impared Wound Healing," S	ociety for Investigative Dermato	logy, 113:375-383, (1999).	
	вн	Lindsey, H., "Modified cold virus kills	s colon cancer," Lancet Oncolog	y, 3(5):264, (2002).	
	BI	Lopez-Guerrero, J., et al., "Modulation virus expressing the human 60-kilodal 4231, (1993).	Iton heat shock protein," Infectio	n and Immunity, 61(10):4225-	
	ВЈ	Lutz, R. and H. Bujard, "Independent via the LacR/O, the TetR/O and AraC. 1210, (1997).	/I <sub>1</sub> -I <sub>2</sub> regulatory elements," Nucl	eic Acids Research, 25:1203-	
	BK	Macdonald, T., "Viral vectors express disease," Gut, 42:460-461, (1998).			
	BL	McCluskie, M., et al., "Route and met in mice and non-human primates," Mc	olecular Medicine, 5:287-300, (1	999).	
	ВМ	Meuli, M., et al. "Efficient gene expre Journal of Investigative Dermatology,		ing local plasmid injection,"	

Examiner Signature	Date Considered
EXAMINER: Initial if citation considered, whether or not citation is in co	nformance with MPEP 609; Draw line through citation if not in

conformance and not considered. Include copy of this form with next communication to applicant.

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		d Publications for Applicant's n Disclosure Statement	Applicant Aladar Szalay et al.	1		
(37 CFR §1.98	B(b))		Filing Date May 19, 2004	Group Art Unit 1633		
	Other D	ocuments (include Author, 1	Fitle, Date, and Place o	of Publication)		
Examiner Initial	Desig. ID		Document			
	BN	Moats, R., et al., "A 'smart' magnetic a activity," Angewandte Chemie, 36(7):	:726-728, (1997).			
	во	Mutschler, E., et al., "Chemotherapy of malignant tumors" in: Drug Actions: Basic Principles and Therapeutic Aspects (medpharm (CRC Press), Suttgart, 595-612, (1995).				
	BP	Pfeifer, A. and I. Verma, "Gene theraph Human Genetics, 2:177-211, (2001).	py:promises and problems," An	nual Review of Genomics and		
	BQ	Rosengart, T., et al. "Six-month assessment of a phase I trial of angiogenic gene therapy for the treatment of coronary artery disease using direct intramyocardial administration of an adenovirus vector expressing the VEGF121 cDNA," Annals of Surgery, 230:466-472, (1999).				
	BR	Rubanyi, G., et al., "The future of hun 142, (2001).	nan gene therapy," Molecular A	spects of Medicine, 22:113-		
	BS	Ruffini, F., et al., "Fibroblast growth factor-II gene therapy reverts the clinical course and the pathological signs of chronic experimental autoimmune encephalomyelitis in C57BL/6 mice," Gene Therapy, 8:1207-1213, (2001).				
	ВТ	Spencer, B., et al., "Herpes simplex vi Investigative Ophthalmology & Visua				
	BU	Wahl, R., et al., "Improved radioimag Nuclear Medicine, 24:316-325, (1983	).			
	BV	Wirtz, S., et al., "Efficient gene delivery to the inflamed colon by local administration of recombinant adenoviruses with normal or modified fibre structure," Gut, 44:800-807, (1999).				

Examiner Signature	Date Considered ,	

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